

Rejection Under 35 U.S.C. § 112, First Paragraph

Claims 1-5 and 7-10 have been rejected under 35 U.S.C. § 112, first paragraph, for lack of written description. The Examiner contends that the specification does not convey that Applicants had possession of the claimed invention at the time of filing. This rejection is respectfully traversed.

The present invention is based on the discovery that co-expression of Factor VII and Kex 2 enzymatic activity results in enhanced secretion of the zymogen form of Factor VII. The specification provides three examples of proteins having Kex 2 enzymatic activity: Kex 2 itself; a carboxyterminally-truncated form of Kex 2; and a Kex 2 to which has been added an endoplasmic reticulum-specific retention signal. The recitation of these variations on Kex 2 unambiguously illustrates that the important element of Kex 2 for the present invention is its enzymatic activity (which is described in the specification at page 3, lines 21-30).

Clearly, one of ordinary skill in the art, based on the present specification, would recognize that Applicants, at the time of filing, had possession of the claimed invention, i.e., a method for expression of Factor VII in the context of a mammalian cell that also expresses Kex 2 enzymatic activity.

It is respectfully pointed out that the claims are not directed to a family of proteins having Kex 2 activity; thus, the issue raised by the Examiner of Applicants allegedly not being "in possession of the claimed genus" is irrelevant. At the time of filing of the present application, identification and/or creation of proteins having Kex 2 activity would have been routine for those of ordinary skill in the art. This fact, in combination with the clear disclosure of the central role of Kex 2 enzymatic activity in the claimed method for producing Factor VII, means that, by any standard¹, Applicants have more than satisfied the written description requirement by requiring that the protease co-expressed with Factor VII possess Kex 2 activity.

¹ See, e.g., *Hyatt v. Boone*, 47 USPQ2d (Fed. Cir., 1998), which discusses the equivalence of various judicial standards for satisfying the written description requirement, such as, e.g., "convey with reasonable clarity" or "reasonably convey" that Applicant was in possession of the invention, or, describe the invention so that "persons of ordinary skill in the art will recognize from the disclosure that Applicants invented processes including those limitations".

On the basis of the above remarks and document, it is believed that the claims are in condition for allowance, and a determination to that effect is earnestly solicited.

Respectfully submitted,

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